CONSENT FORM CHECK LIST (Human Research)

Requirements from Calif. H & S Code Section 24170 et. Seq and Title 45 CFR Part 46

Informed Consent Element	Page-Line

The consent form provides:

1. Fair explanation of procedures

    a. purpose of experiment _____

    b. identification of experimental aspects _____
    For example, "My standard medication will be replaced by:..."

    c. nature of drugs and dosages, route of administration _____

    d. extent of experience with investigational drug _____

    e. special procedures (e.g., venipuncture) _____

    f. duration of participation and estimated recovery time after experiment _____

2. Name, affiliation & address of person responsible for experiment _____

3. Name of principal investigator, funding source, manufacturer, authorizing organization _____

4. Investigator's offer to answer any questions _____

5. Name, address & phone number of impartial third party for addressing complaints _____

    Note: The Panel requires the name, address and phone number of a qualified office or individual that has been designated by the research institute or sponsor to have responsibility and authority to follow up on complaints.

6. Risks to subject

    a. discomforts _____

    b. drug side effects _____

    c. undiscovered drug toxicity _____

    d. long-term effects that cannot be known _____

    e. special risks in case of pregnancy (or possible pregnancy) _____

Informed Consent Element	Page-Line
7. Possible benefits	
a. therapeutic	_____
b. benefit (or none) to subject	_____
c. to society (e.g., scientific knowledge)	_____
d. to a principal investigator of the research, the research institution or a manufacturer	_____
8. Voluntary participation	
a. clearly stated	_____
b. special risk populations	_____
c. may withdraw from experiment without penalty	_____
9. Disclosure of compensation	
a. to investigator by study sponsor (if applicable)	_____
b. to subject for participation in study (if applicable)	_____
10. Alternative procedures (drugs) for therapy	_____
11. Policy regarding treatment and compensation provisions for injured research subjects	_____
12. Confidentiality statement	_____

Note: The Panel requires that a statement be included in the consent advising potential research subjects that their records may be inspected by the Research Advisory Panel; or , “State or Federal Regulatory Agencies”.

13. Language	
a. no exculpatory phrases	_____
b. understandable to lay person (avoid or explain technical terms)	_____
c. written in the language comprehended by subject	_____
d. clearly written, no ambiguous phrases	_____

Informed Consent Element	Page-Line
14. Signature by subject	_____
15. Signature by person administering consent to attest to adhering to informed consent procedures	_____
16. Copies of consent form and separate Bill of Rights will be given to subject	_____